

Notice of Allowability**Application No.**

09/663,889

Examiner

Robert M. Kelly

Applicant(s)

NABEL ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/18/05.
2. ☒ The allowed claim(s) is/are 17 and 20-36.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>9/18/00</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Art Unit: 1633

Note: status of claims prior to amendment

Applicant's submission of 11/18/05 is entered.

Claim 17 is amended.

Claim 19 is cancelled.

Claims 17 and 20-36 are presently pending.

Information Disclosure Statement

During a review of the prosecution history of this Application, the Examiner has become aware that the US and foreign patent documents cited in the PTO-1449 of 9/18/00 were not initialed by the Examiner. The Examiner has provided another copy of this IDS, wherein such references have been initialed by the Examiner.

EXAMINER'S AMENDMENT

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 2/10/06, Mr. John Murray requested an extension of time for 2 MONTH(S) and authorized the Director to charge Deposit Account No. 23-1925 the required fee of \$450.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Art Unit: 1633

The application has been amended as follows:

IN THE TITLE:

1. The title has been amended as follows:

KitsA combination for site-specifically transforming cells in vivo comprising a double-balloon catheter and a nucleic acid comprising a gene encoding p21.

IN THE ABSTRACT

2. The abstract has been deleted and replaced with the following:

The present invention provides a combination including a double-balloon catheter and a nucleic acid encoding the cyclin dependent kinase inhibitor p21. The nucleic acid may also encode HLA-B7, an immunotherapeutic agent, a cytokine or a prodrug converting enzyme.

The following is an examiner's statement of reasons for allowance:

1. Applicant's cancellation of claim 19 moots all rejections of such claim, and thus the rejections are withdrawn.
2. Applicant's amendment of the independent claim, claim 17 to double-balloon catheters overcomes the objection to priority, and requirement for a new oath and/or declaration.
3. Applicant's amendment of the independent claim, claim 17 to double-balloon catheters overcomes the rejections of:
 - (a) claims 17 and 20-36 for comprising new matter (Official Action of 9/9/05, pp.

6-10);

(b) claims 17 and 20-36 for being anticipated by Nabel (Official Action of 9/9/05, p. 10);

(c) claims 17, 20-24, 26-27, and 31 for being anticipated by Eastham (Official Action of 9/9/05, pp. 11-12).

Specifically, Applicant's specification and priority documents, including the Nabel document used in the rejection of claims 17 and 20-23 teach the use of double-balloon catheters to deliver the transgenes of the invention, as claimed, and as such meet the requirement of possession of the claimed composition. Therefore, Applicant has possession, and such possession and requirements under 35 USC 112, first paragraph are shown for Applicant's priority claim. Hence, the rejections under Nabel, because Nabel is a priority document, are withdrawn, Applicant's priority is acknowledged for the claimed invention, and the new matter rejections are withdrawn. With regard to the Eastham rejections of claims 17, 20-24, 26-27, and 31, Eastham teaches the administration of vectors comprising the p21 gene directly to a tumor, and thus the Artisan would not consider using a double balloon catheter. Such double-balloon catheters are recognized in the art as for the purpose of delivering substances into arterial tissues (e.g., U.S. Patent No. 5,652,225, col. 1, paragraph 5), and even Applicant's specification discloses that the invention is for treatment of restinosis caused by administration of such catheters (p. 11, paragraph 2). Hence, the Artisan would not have been motivated to modify the methods of Eastham with any art using a double-balloon catheter, as the tumor tissue is not even vascular tissue, and Eastham teaches direct administration to the tumor. Therefore, it would not even have been obvious to use such double-balloon catheter in the method of Eastham. Moreover, because the totality of the prior art teaches that direct administration to tumors is the

Art Unit: 1633

route of administration of vectors to treat tumors, e.g., Eastham, the Artisan would not have been motivated to treat a tumor with a double-balloon catheter, which would be treatment via arterial supply. Hence, the totality of the prior art does not teach nor suggest Applicant's claimed invention.

Conclusion

Having overcome all rejections and/or objections to all pending claims, and the fact that the art of record does not demonstrate that Applicant's invention is obvious or anticipated, Claims 17 and 20-36 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

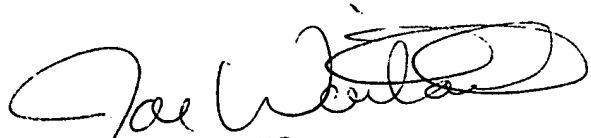
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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